UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 16, 1992

MEMORANDUM

SUBJECT: Interpretation of the Good Laboratory Practice (GLP) Regulation

GLP Regulations Advisory No. 52

FROM: David L. Dull, Director
Laboratory Data Integrity Assurance Division

TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Policy & Grants Division of the Office of Compliance Monitoring. This interpretation is official policy in the GLP program and should be followed by all GLP inspectors.

For further information, please contact Francisca E. Liem at (703) 308-8333.

Attachment

cc: M. Stahl
C. Musgrove

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF ENFORCEMENT

MEMORANDUM

SUBJECT: Good Laboratory Practice Regulations Legal Issue

FROM: Michael J. Walker, Enforcement Counsel
Pesticides and Toxic Substances

TO: David L. Dull, Director
Laboratory Data Integrity Assurance Division

My office has received your August 24, 1992 memorandum in which you request a legal opinion as to the appropriate functions of the Quality Assurance Unit under the Good Laboratory Practice regulations at 40 CFR 160.35. Specifically, you asked whether any of the activities of study director, quality assurance unit and testing facility management can be conducted by the same person.

40 CFR 160.35(a) sets forth that, "[f]or any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study." The regulations do not place a similar restriction upon the roles of testing facility management nor study director.

It is our position that the regulation allows the study director and/or the testing facility management to have more than one role. For example, a study director who is also the president of the company is not in violation of the regulation. However, we feel that the regulation prohibits the personnel assigned to the quality assurance unit from performing any other function at the testing facility which may impact a study. Therefore, members of the quality assurance unit cannot work on any aspect of a study, even in an advisory capacity; cannot be a study director; cannot be part of testing facility management.

In your memorandum you raise a question concerning the compliance status of a testing facility where the quality assurance employee is married to the study director or the president of the company. You are justified in suspecting a possible violation of 40 CFR 160.35(a). This situation, however, is not a violation of the regulation per se. The regulation only requires the quality assurance unit to maintain independence and separateness for any given study. Therefore, the inspector should try to document the steps taken by the testing facility to insure compliance with the quality assurance unit requirement of independence and separateness For example, request a copy of an SOP which states that Husband

cannot perform quality assurance functions for any given study conducted by Wife. Then follow-up this SOP by requesting documentation as to the employees who worked on any given study to make sure that they are adhering to the SOP.

If you have any further questions concerning tho proper roles of the quality assurance unit, study director or testing facility management do not hesitate to contact Helene Ambrosino of my staff at (202) 260-0239.

cc: Jon Jacobs
Helene Ambrosino
Cindy Coldiron